



Complete Summary

TITLE

Rheumatoid arthritis: percentage of patients in the third trimester of pregnancy for whom non-steroidal anti-inflammatory drugs (NSAIDs) (selective and non-selective) and aspirin are not used.

SOURCE(S)

Khanna D, Arnold EL, Pencharz JN, Grossman JM, Traina SB, Lal A, MacLean CH. Measuring process of arthritis care: the Arthritis Foundation's quality indicator set for rheumatoid arthritis. *Semin Arthritis Rheum*2006;35:211-237.

MacLean CH, Saag KG, Solomon DH, Morton SC, Sampsel S, Klippel JH. Measuring quality in arthritis care: methods for developing the Arthritis Foundation's quality indicator set. *Arthritis Rheum*2004 Apr 15;51(2):193-202. [PubMed](#)

Measure Domain

PRIMARY MEASURE DOMAIN

Process

The validity of measures depends on how they are built. By examining the key building blocks of a measure, you can assess its validity for your purpose. For more information, visit the [Measure Validity](#) page.

SECONDARY MEASURE DOMAIN

Does not apply to this measure

Brief Abstract

DESCRIPTION

This measure is used to assess the percentage of patients in the third trimester of pregnancy for whom non-steroidal anti-inflammatory drugs (NSAIDs) (selective and non-selective) and aspirin are not used.

RATIONALE

Non-steroidal anti-inflammatory drug (NSAID) and aspirin use in the third trimester are associated with adverse maternal and fetal events.

PRIMARY CLINICAL COMPONENT

Rheumatoid arthritis; pregnancy; non-steroidal anti-inflammatory drugs (NSAIDs); aspirin

DENOMINATOR DESCRIPTION

Patients with a diagnosis of rheumatoid arthritis who are in the third trimester of pregnancy

NUMERATOR DESCRIPTION

Patients for whom non-steroidal anti-inflammatory drugs (NSAIDs) (selective and non-selective) and aspirin are not used

Evidence Supporting the Measure

EVIDENCE SUPPORTING THE CRITERION OF QUALITY

- A clinical practice guideline or other peer-reviewed synthesis of the clinical evidence
- A formal consensus procedure involving experts in relevant clinical, methodological, and organizational sciences
- One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Evidence Supporting Need for the Measure

NEED FOR THE MEASURE

Unspecified

State of Use of the Measure

STATE OF USE

Current routine use

CURRENT USE

Internal quality improvement

Application of Measure in its Current Use

CARE SETTING

Ambulatory Care
Physician Group Practices/Clinics

PROFESSIONALS RESPONSIBLE FOR HEALTH CARE

Physicians

LOWEST LEVEL OF HEALTH CARE DELIVERY ADDRESSED

Individual Clinicians

TARGET POPULATION AGE

Women of childbearing age

TARGET POPULATION GENDER

Female (only)

STRATIFICATION BY VULNERABLE POPULATIONS

Unspecified

Characteristics of the Primary Clinical Component**INCIDENCE/PREVALENCE**

Rheumatoid arthritis (RA) affects one percent of the adult population. RA affects approximately 2.5 million Americans, disproportionately women.

EVIDENCE FOR INCIDENCE/PREVALENCE

Alarcon GS. Epidemiology of rheumatoid arthritis. Rheum Dis Clin North Am 1995 Aug;21(3):589-604. [144 references] [PubMed](#)

Hochberg MC, Spector TD. Epidemiology of rheumatoid arthritis: update. Epidemiol Rev 1990;12:247-52. [48 references] [PubMed](#)

Hochberg MC. Adult and juvenile rheumatoid arthritis: current epidemiologic concepts. Epidemiol Rev 1981;3:27-44. [129 references] [PubMed](#)

Lawrence RC, Helmick CG, Arnett FC, Deyo RA, Felson DT, Giannini EH, Heyse SP, Hirsch R, Hochberg MC, Hunder GG, Liang MH, Pillemer SR, Steen VD, Wolfe F. Estimates of the prevalence of arthritis and selected musculoskeletal disorders in the United States. Arthritis Rheum 1998 May;41(5):778-99. [PubMed](#)

McDuffie FC. Morbidity impact of rheumatoid arthritis on society. Am J Med 1985 Jan 21;78(1A):1-5. [PubMed](#)

ASSOCIATION WITH VULNERABLE POPULATIONS

See the "Burden of Illness" and "Incidence/Prevalence" fields.

BURDEN OF ILLNESS

- Forty percent of patients with early rheumatoid arthritis (RA) (less than six months of symptoms) have erosive disease at presentation and remission is rare (less than 5%).
- NSAIDs are not known to be teratogenic in humans. Whereas many of the newer agents have not been studied in depth, data for indomethacin, naproxen, ketoprofen, and ibuprofen are available. As prostaglandin synthesis inhibitors, they have the potential to inhibit uterine contractions and therefore prolong gestation and labor. Similarly, this inhibition increases the risk in the fetus of premature closure of the ductus arteriosus, pulmonary hypertension, impaired renal function, and, consequently, reduction in urine output and amniotic fluid. The antiplatelet effects of NSAIDs increase the risk of peripartum blood loss and anemia in the mother and in the fetus increase the risk of cutaneous and intracranial bleeding. These adverse effects are found to be less common when therapy has been discontinued six to eight weeks before delivery.

Aspirin, which crosses the placenta, rarely causes congenital anomalies in humans compared to animals. An increased incidence of cleft palate and other congenital anomalies has failed to be demonstrated by several large prospective studies. Low-dose aspirin used for its antiplatelet effect appears to be safe throughout pregnancy. However, anti-inflammatory doses prolong gestation and labor in the mother by inhibiting uterine contractions as well as increase the risk of antepartum and postpartum bleeding and anemia. In the fetus high doses of aspirin can cause premature closure of the ductus arteriosus, increased risk of intracranial hemorrhage and transient renal failure and oligohydramnios. Recommendations are to discontinue aspirin (high dose) at least four to eight weeks before delivery to avoid these possible adverse effects.

EVIDENCE FOR BURDEN OF ILLNESS

Arcilla RA, Thilenius OG, Ranniger K. Congestive heart failure from suspected ductal closure in utero. *J Pediatr* 1969 Jul;75(1):74-8. [PubMed](#)

Cantor B, Tyler T, Nelson RM, Stein GH. Oligohydramnios and transient neonatal anuria: a possible association with the maternal use of prostaglandin synthetase inhibitors. *J Reprod Med* 1980 May;24(5):220-3. [PubMed](#)

Collins E, Turner G. Maternal effects of regular salicylate ingestion in pregnancy. *Lancet* 1975 Aug 23;2(7930):335-8. [PubMed](#)

Hannonen P, Mottonen T, Hakola M, Oka M. Sulfasalazine in early rheumatoid arthritis. A 48-week double-blind, prospective, placebo-controlled study. *Arthritis Rheum* 1993 Nov;36(11):1501-9. [PubMed](#)

Harrison BJ, Symmons DP, Brennan P, Barrett EM, Silman AJ. Natural remission in inflammatory polyarthritis: issues of definition and prediction. *Br J Rheumatol* 1996 Nov;35(11):1096-100. [21 references] [PubMed](#)

Janssen NM, Genta MS. The effects of immunosuppressive and anti-inflammatory medications on fertility, pregnancy, and lactation. Arch Intern Med 2000 Mar 13;160(5):610-9. [99 references] [PubMed](#)

Jick H, Holmes LB, Hunter JR, Madsen S, Stergachis A. First-trimester drug use and congenital disorders. JAMA 1981 Jul 24-31;246(4):343-6. [PubMed](#)

Ostensen M. Safety on NSAID's during pregnancy and lactation. Immunopharmacology 1996;4:31-41.

Slone D, Siskind V, Heinonen OP, Monson RR, Kaufman DW, Shapiro S. Aspirin and congenital malformations. Lancet 1976 Jun 26;1(7974):1373-5. [PubMed](#)

UTILIZATION

Over nine million physician visits and greater than 250,000 hospitalizations are attributed to rheumatoid arthritis (RA) per year.

EVIDENCE FOR UTILIZATION

Allaire SH, Prashker MJ, Meenan RF. The costs of rheumatoid arthritis. Pharmacoeconomics 1994 Dec;6(6):513-22. [69 references] [PubMed](#)

Cooper NJ. Economic burden of rheumatoid arthritis: a systematic review. Rheumatology (Oxford) 2000 Jan;39(1):28-33. [33 references] [PubMed](#)

COSTS

Rheumatoid arthritis (RA) has significant economic implications for the individual patient, as well as for society. Individuals with RA have 3 times the direct medical costs, twice the hospitalization rate and 10 times the work disability rate on an age- and sex-matched population. A recent study has shown annual medical costs for a patient with RA to be approximately \$8,500. Annual costs rise as the duration of the disease increases and as function declines. Indirect costs related to disability and work loss have been estimated to be 3 times higher than the direct costs associated with the disease.

EVIDENCE FOR COSTS

American College of Rheumatology Subcommittee on Rheumatoid Arthritis. Guidelines for the management of rheumatoid arthritis: 2002 Update. Arthritis Rheum 2002 Feb;46(2):328-46. [PubMed](#)

Institute of Medicine National Healthcare Quality Report Categories

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Safety

Data Collection for the Measure

CASE FINDING

Users of care only

DESCRIPTION OF CASE FINDING

Patients with a diagnosis of rheumatoid arthritis who are in the third trimester of pregnancy

DENOMINATOR SAMPLING FRAME

Patients associated with provider

DENOMINATOR INCLUSIONS/EXCLUSIONS

Inclusions

Patients with a diagnosis of rheumatoid arthritis who are in the third trimester of pregnancy

Exclusions

Unspecified

RELATIONSHIP OF DENOMINATOR TO NUMERATOR

All cases in the denominator are equally eligible to appear in the numerator

DENOMINATOR (INDEX) EVENT

Clinical Condition

DENOMINATOR TIME WINDOW

Time window follows index event

NUMERATOR INCLUSIONS/EXCLUSIONS

Inclusions

Patients for whom non-steroidal anti-inflammatory drugs (NSAIDs) (selective and non-selective) and aspirin are not used

Exclusions

Unspecified

MEASURE RESULTS UNDER CONTROL OF HEALTH CARE PROFESSIONALS, ORGANIZATIONS AND/OR POLICYMAKERS

The measure results are somewhat or substantially under the control of the health care professionals, organizations and/or policymakers to whom the measure applies.

NUMERATOR TIME WINDOW

Episode of care

DATA SOURCE

Administrative data
Medical record
Pharmacy data

LEVEL OF DETERMINATION OF QUALITY

Individual Case

PRE-EXISTING INSTRUMENT USED

Unspecified

Computation of the Measure

SCORING

Rate

INTERPRETATION OF SCORE

Better quality is associated with a higher score

ALLOWANCE FOR PATIENT FACTORS

Unspecified

STANDARD OF COMPARISON

Internal time comparison

Evaluation of Measure Properties

EXTENT OF MEASURE TESTING

Using a modification of the RAND Corporation/University of California Los Angeles (RAND/UCLA) Appropriateness Method, a multi-disciplinary expert panel

comprised of nationally recognized experts in arthritis, primary care, and pain management discussed and rated the validity of each of the proposed measures based on 1) a summary of the evidence to support or refute each proposed measure and 2) their expert opinion.

EVIDENCE FOR RELIABILITY/VALIDITY TESTING

Khanna D, Arnold EL, Pencharz JN, Grossman JM, Traina SB, Lal A, MacLean CH. Measuring process of arthritis care: the Arthritis Foundation's quality indicator set for rheumatoid arthritis [in press]. *Semin Arthritis Rheum*:1-71.

MacLean CH, Saag KG, Solomon DH, Morton SC, Sampsel S, Klippel JH. Measuring quality in arthritis care: methods for developing the Arthritis Foundation's quality indicator set. *Arthritis Rheum* 2004 Apr 15;51(2):193-202. [PubMed](#)

Identifying Information

ORIGINAL TITLE

Quality indicator 25. Reproductive issues.

MEASURE COLLECTION

[The Arthritis Foundation's Quality Indicator Project](#)

MEASURE SET NAME

[The Arthritis Foundation's Quality Indicator Set for Rheumatoid Arthritis](#)

SUBMITTER

Arthritis Foundation

DEVELOPER

Arthritis Foundation
RAND Health

ADAPTATION

Measure was not adapted from another source.

RELEASE DATE

2005 Jan

MEASURE STATUS

This is the current release of the measure.

SOURCE(S)

Khanna D, Arnold EL, Pencharz JN, Grossman JM, Traina SB, Lal A, MacLean CH. Measuring process of arthritis care: the Arthritis Foundation's quality indicator set for rheumatoid arthritis. *Semin Arthritis Rheum* 2006;35:211-237.

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MEASURE AVAILABILITY

The individual measure, "Quality Indicator 25. Reproductive Issues," is published in "Measuring Process of Arthritis Care: The Arthritis Foundation's Quality Indicator Set for Rheumatoid Arthritis."

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NQMC STATUS

This NQMC summary was completed by ECRI on October 25, 2006. The information was verified by the measure developer on February 1, 2007.

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